

REMARKS/ARGUMENTS

Favorable reconsideration of this application, in light of the present amendment and following discussion, is respectfully requested.

Claims 6 and 9-25 are pending. Claim 6 is amended, and Claims 1-5, 7, and 8 are canceled. Support for the amendment to Claim 6 can be found at page 6, line 15-page 8, line 4 of the specification, for example. No new matter is added.

In the outstanding Office Action, Claims 6 and 8-16 were rejected under 35 U.S.C. § 103(a) as obvious over Usui (U.S. Patent No. 5,879,378, hereafter “Usui”) in view of Miyashita (U.S. Patent No. 5,233,981, hereafter “Miyashita”), in further view of Kuratomi et al. (U.S. Patent No. 4,747,841, hereafter “Kuratomi”) in further view of Koiso et al. (U.S. Patent No. 5,425,975, hereafter “Koiso”). Claim 17 was rejected under 35 U.S.C. § 103(a) as obvious over Usui in view of Miyashita and further in view of Kuratomi and further in view of Koiso and further in view of Kamiyama (U.S. Patent No. 6,669,953, hereafter “Kamiyama”). Claim 18 was rejected under 35 U.S.C. § 103(a) as obvious over Usui in view of Miyashita in further view of Kuratomi in further view of Koiso and in further view of Betrabet et al. (U.S. Patent No. 5,618,281, hereafter “Betrabet”). Claim 19 was rejected under 35 U.S.C. § 103(a) as obvious over Usui in view of Miyashita, in view of Kuratomi, in view of Koiso, and in further view of Hoffman et al. (U.S. Patent No. 6,190,689, hereafter “Hoffman”). Claim 20 was rejected under 35 U.S.C. § 103(a) as obvious over Usui in view of Miyashita, in view of Kuratomi, in view of Koiso, and further in view of Effing et al. (U.S. Patent No. 6,193,996, hereafter “Effing”). Claim 21 was rejected under 35 U.S.C. § 103(a) as obvious over Usui in view of Miyashita, in view of Kuratomi, in view of Koiso, and further in view of Basedow et al. (U.S. Patent No. 6,198,017, hereafter “Basedow”). Claims 23 and 24 were rejected under 35 U.S.C. § 103(a) as obvious over Usui, in view of Miyashita, in view of Kuratomi, in view of Koiso, and further in view of Tsutsumi (U.S. Patent No.

6,841,716, hereafter "Tsutsumi"). Claim 22 was indicated as reciting allowable subject matter.

Applicants acknowledge with appreciation the indication that Claim 22 recites allowable subject matter.

Regarding the rejection of Claims 6 and 8-16 as obvious over Usui in view of Miyashita, in further view of Kuratomi, and in further view of Koiso, that rejection is respectfully traversed by the present response.

Amended Claim 6 recites:

A steam generator comprising:

**a steam generation portion comprising a steam-generating composition and pulp fiber** as a support so as to inhibit movement of the steam generating composition, the steam-generating composition including a metal powder, activated carbon and a salt to be reacted with water and adapted to discharge steam as the metal powder is oxidized; and

an adhesive layer provided on a surface of the steam generator adapted to be applied to at least one of skin or mucosa of a user of the steam generator,

wherein the steam-generating composition is disposed in pore-like structures of a paper sheet and the adhesive layer includes at least one opening through which the steam or water vapor is discharged from the steam-generating composition.

(Emphasis added). Accordingly, an oxidation reaction of iron in a steam-generating portion creates steam or water vapor which is discharged from the steam-generating composition through at least one opening in an adhesive layer. The steam is thus applied to the skin or mucosa. The steam generation portion includes a steam generation composition and pulp fiber. The steam generation portion is formed by using a paper-making process to combine the steam-generation composition with pulp fiber. As a result, the steam-generating composition can be formed in the form of paper sheet. One benefit of forming the steam-generating portion as a paper sheet is that the steam generator can be made extremely thin or flexible, and the steam-generating composition can be disseminated in a high density,

uniform layer. This paper-like steam-generating composition has a high degree of freedom in respect of a shape, and accordingly, heat-characteristics thereof can be controlled.

In contrast, the cited references, Usui or Koiso, only **add** powder to an **existing** sheet.

Usui uses paper for supporting powder in order to prevent uneven distribution of the exothermic composition. Usui states:

**The most significant character of the invention is that the exothermic composition is formed in layers comprising at least one exothermic reaction layer coated on a film or sheet and at least one reaction auxiliary layer coated on and/or under the exothermic reaction layer on the film or sheet.<sup>1</sup>**

Usui additionally states:

Further, as a laminate film or laminate sheet to be laminated on **the laminate film or laminate sheet on which the exothermic composition has been laminated**, it is recommendable to use a film or sheet having a three-layer structure with paper, woven fabric, nonwoven fabric or foam sheet disposed inwardly of the pouch, woven fabric, nonwoven fabric or foam sheet disposed outwardly, and a gas-permeable film of a polymeric material sandwiched between these two layers, in order to enhance feel.<sup>2</sup>

Accordingly, Usui requires an exothermic composition to be deposited onto a laminate film or sheet.

In Koiso, a heat-generating substance is dispersed and retained in the pores of a non-woven fabric by vibrating the composition and supporting substances. Similar to the structure described in Usui, the heat-generating substance of Koiso is added to a pre-existing non-woven fabric. In other words, the heat-generating substance is deposited **onto** a substrate, but is not part of the substrate itself. For example, Koiso teaches that the heat-generating substance is **sandwiched between** non-woven fabrics and compression-molded.<sup>3</sup>

Miyashita does not remedy the deficiencies in Usui and Koiso discussed above.

Rather, Miyashita describes a heating composition sealed inside a flat bag.<sup>4</sup> Nowhere in

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<sup>1</sup> Usui, col. 4, lines 35-39 (emphasis added).

<sup>2</sup> Usui, col. 5, lines 49-57 (emphasis added).

<sup>3</sup> See Koiso, Fig. 1.

<sup>4</sup> Miyashita, col. 5, line 63-col. 4, line 4.

Miyashita is a steam generation portion comprising a steam-generating composition and pulp fiber disclosed.

Kuratom describes a pyrogen (5) inside a bag body (4), but, like the references discussed above, does not disclose a steam generation portion comprising a steam-generating composition and pulp fiber.

Kamiyama is directed to copolymers with drug retention properties and discloses none of the physical structure recited in amended Claim 6, much less a steam generation portion comprising a steam-generating composition and pulp fiber.

Betrabet describes an absorbent layer disposed between a permeable topsheet and a backsheet. Like all the references discussed above, Betrabet fails to disclose a steam generation portion comprising a steam-generating composition and pulp fiber.

Hoffman, Effing, Basedow, and Tsutsumi all relate to therapeutics involving adhesives and do not disclose in any way a steam generation portion comprising a steam-generating composition and pulp fiber.

Accordingly, Applicants respectfully submit that none of Usui, Koiso, Miyashita, and Kuratom discloses a steam generation portion including both pulp fiber and a steam generating composition, and none of the references cited against dependent claims remedies the deficiencies of Usui, Koiso, Miyashita, and Kuratom discussed above. Accordingly, Applicants respectfully submit that amended Claim 6 patentably distinguishes over the cited references for at least the reasons discussed above.

Applicants further respectfully submit that dependent Claims 9-25 depending, directly or indirectly, from amended Claim 6 patentably distinguish over the cited references for at least the same reasons as amended Claim 6.

Applicants wish to make the following additional remarks regarding Kuratom, relied on in the outstanding Office Action for the feature of “at least one opening through which the

steam or water vapor is discharged from the steam-generating composition”. As Kuratomi fails to mention passing steam or water vapor through the holes, Applicants interpret the statement in the outstanding Office Action at page 3, item 4 to mean that the outstanding Office Action deems the holes (11) or (13) of Kuratomi to inherently be configured to pass steam or water vapor.

Applicants respectfully submit that the standard for inherency is whether a person of ordinary skill in the art would deem that the characteristic in question **must** be present in the cited reference.<sup>5</sup> However, “[t]he fact that a certain result of characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.”<sup>6</sup> Moreover:

to establish inherency, the extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”<sup>7</sup>

Finally, as set forth in MPEP § 2112, “in relying upon the theory of inherency, the Examiner **must** provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.”<sup>8</sup>

The present invention contains the steam-generating composition which generates a considerable amount of water vapor or water deposits. Therefore, in the present invention, in order to enhance the adhesive force of the adhesive layer while still allowing steam to reach the skin, the adhesive layer has at least one opening through which steam or water vapor may pass.

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<sup>5</sup> MPEP § 2112.

<sup>6</sup> MPEP § 2112 citing In re Rijckaert, 9 F.3d 1531, 1534, 28 U.S.P.Q.2d 1955, 1957 (Fed. Cir. 1993).

<sup>7</sup> MPEP § 2112 citing In re Robertson, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999).

<sup>8</sup> MPEP § 2112 citing Ex party Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

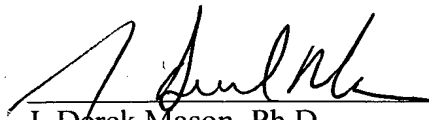
With respect to the adhesive layer, Kuratomi discloses an herbal mixture heated via a pyrogen and develops organics that are delivered to the skin surface. The herbal mixture, in the case of Kuratomi (preferably moxa), has a very low water content. Kuratomi does not disclose that water vapor or steam is produced from the herbal mixture. Applicants respectfully submit that water vapor produced from the herbal mixture is negligible. The purpose of the holes described in Kuratomi is merely to allow air to reach the pyrogen and to allow vapor from the moxa to reach the skin when the moxa is heated by the pyrogen. Accordingly, Applicants respectfully submit that it is unlikely (and certainly not inherent) that the holes of Kuratomi would allow steam or water vapor to pass through the adhesive as recited in amended Claim 6.

Therefore, the holes described in Kuratomi do not qualify as "at least one opening through which the steam or water vapor is discharged from the steam-generating composition" as recited in amended Claim 6, and Applicants respectfully submit that Claim 6 patentably distinguishes over the cited references for at least this additional reason.

Consequently, in view of the present amendment and foregoing discussion, it is respectfully submitted that the present application is in condition for allowance. An early and favorable action to that effect is respectfully requested.

Respectfully submitted,

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